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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,456	09/21/2001	Tully Michael Underhill	9611-26	2501

7590

05/03/2004

Micheline Gravelle
Bereskin & Parr
Box 401
40 King Street West
Toronto, ON M5H 3Y2
CANADA

EXAMINER

KAUSHAL, SUMESH

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/957,456

Applicant(s)

UNDERHILL ET AL.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1, 4-10, 12 and 13.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

JEFFREY FREDMAN
PRIMARY EXAMINER

Continuation of 2. NOTE: Amendment of claim 1, which recites claim limitation “a nucleic acid construct comprising a reporter gene that comprises a sequence upstream of the promoter from the type II collagen gene (Col2a1) that binds to the transcription factor Sox9 that is endogenous to the cells” would require additional search and/or consideration under 35 USC 102 and 103 regarding prior art issues.

Continuation of 3. Applicant's reply has overcome the following rejection(s): Claims 1-8 and 12-13 under 35 USC 112(1) regarding enablement and written description issues.

Continuation of 5. does NOT place the application in condition for allowance because:

The finality of earlier office action is proper because newly raised enablement and written description rejection were the result of newly introduced claimed subject matter that has not been proposed before. Please see the claims submitted on 07/22/03 and 09/21/01, wherein the amendment to claim 1 prompted rejections under written description and enablement issues.

Claim 9 and 10 stand rejected under 35 USC 112(1) regarding enablement and written description issues for the claim limitation pGL3(4X48). The instant specification fails to meet written description requirement for the deposited biological material. see Deposit of Biological Materials for Patent Purposes, Final Rule, 54 FR 34,864 (August 22, 1989). In instant case applicant's referral to the pGL3(4X48) on page 17 of the specification is insufficient assurance that all written description requirements for the deposited biological material had been met. It is unclear what would be the nucleotide sequence of pGL3(4X48) if a biological deposit had been made. The specification fails to disclose what are the structural and/or functional limitations of pGL3(4X48). In addition, the specification fails to identify any 48-bp fragment (Sox9 response element) that is responsive to transcription factor Sox9. Therefore it is unclear how one skill in the art would exercise the invention as claimed without the disclosure of structural limitations of the claimed pGL3(4X48) construct.

Claims 1, 4-8 and 12-13 stand rejected under 35 USC 103 regarding prior art issues, since newly proposed amendment to claim 1 has not been entered. The applicants argues the prior art rejection in view of newly proposed amendment that has not been entered, since it would require additional search and/or consideration under 35 USC 102 and 103 regarding prior art issues